Specific Aims

The objective of the proposed research is to improve our understanding of emergent and inpatient care following procedural intervention to remove kidney stones. Specifically, we will characterize the incidence, variation and costs for unplanned emergent and inpatient care (i.e., hospital admissions or readmissions and emergency department visits) following interventions to remove renal or ureteral stones [i.e., shock wave lithotripsy (SWL), ureteroscopy (URS), or percutaneous nephrostolithotomy (PNL)]. We will accomplish this by conducting analyses of national private-payer claims data using analytic strategies developed by a fellow and mentor with a successful track record of collaboration with the UDA project. Using a retrospective, claims-based cohort design, we will characterize variations in the utilization and costs of unplanned post-procedural care within 30 days of intervention for stone removal. Our efforts are organized under the following three **specific aims:**

1. **To describe the incidence of hospital admissions, readmissions, and emergency department visits within 30 days of a procedure for stone removal.** Research under Aim 1 will focus on descriptive analyses of emergent and inpatient care following discharge from outpatient or inpatient surgery. Under Aim 1, we will test the following hypothesis:

   The proportion of patients requiring unplanned emergent and inpatient care within 30 days of intervention will vary by stone removal procedure (i.e., SWL, ureteroscopy and PNL).

2. **To characterize variations in utilization of hospital readmissions and emergency department visits following procedures for stone removal.** Research under Aim 2 will focus on descriptive analyses of patient and facility characteristics associated with unplanned care (i.e., hospital readmission and ED visits) following intervention to remove kidney stones. Under Aim 2, we will test the following *hypothesis:*

   Unplanned post-procedural emergent and inpatient care is associated with patient characteristics (specifically, age, gender, and co-morbid conditions) and facility characteristics (specifically volume).

3. **To characterize the incremental costs of unplanned post-procedural care in the surgical management of stone disease.** Research under Aim 3 will utilize multivariable models to identify differences in estimated healthcare expenditures. Related to this outcome, we will test the following *hypotheses:*

   a. *Estimated healthcare expenditures will differ between patients who experience unplanned post-procedural care following a stone removal procedure and those patients who do not experience unplanned post-procedural care.*
   b. *Patient and facility characteristics (as outlined under Aim 2) are associated with the marginal costs for hospital readmission and ED visits.*

Background

Urinary lithiasis imposes a significant burden of disease in the United States. Data from the National Health and Nutrition Examination Survey demonstrate an increase in the prevalence of stone disease from 1976 to 1994, rising from 3.8% to 5.2%.[1] A recently published analysis from the applicant, in collaboration with the Urologic Disease in America team, demonstrates that the prevalence of kidney stones in the United States has risen from 1 in 20 to almost 1 in 11 persons since the mid-1990s, and that this increase is likely related to the surge in obesity in the US population over the same time frame.[2] Up to 50% of stone formers will have a recurrence within 5 years.[3]

Medical expenditures for treating patients with kidney stones are significant. Recent estimates from the Urologic Diseases in America project suggest that aggregate expenditures for treating patients with kidney stones exceed $10 billion annually, making kidney stones one of the most expensive urologic conditions.[4, 5] Little is known regarding the drivers of these expenditures, although charges appear to be greatest for ambulatory surgery and inpatient care.[6]

Unplanned hospital admissions and emergency department visits have recently emerged as an important health policy issue. In particular, government payers are imposing financial penalties for hospital readmissions.[7-9] Unplanned care within 30 days of a stone procedure could occur following either inpatient or ambulatory/outpatient interventions. Patients who undergo inpatient procedures, such as PNL, could be readmitted to hospital or require ED visits for potential complications of surgery. Second, patients who undergo ambulatory/outpatient procedures (i.e., ureteroscopy or SWL) could require hospital admission or ED care for potential complications in the postoperative period. While immediate hospital admission following common urologic office procedures appears less common,[10] 30-day readmission rates, and other unplanned care such as post-procedural ED visits, remain poorly characterized as a potential quality marker and health policy issue in the treatment of patients with kidney stones.

Significance

In order to assess the impact of unplanned post-procedural inpatient and emergent care, we must first understand the incidence of ED visits and hospital readmissions following inpatient procedures as well as ED visits and hospital admissions following outpatient procedures. Research under Aim 1 will describe the incidence of unplanned post-procedural care, and determine whether and how this care varies among different procedures. We must also understand patient, provider and facility characteristics associated with use of unplanned post-procedural care. Research under Aim 2 will characterize utilization of unplanned post-procedural care and inform our understanding of ***healthcare disparities*** in the treatment of patients with kidney stones, and will also form the basis of interventions to potentially reduce unplanned post-procedural care. Research under Aim 3 will characterize the financial impact of unplanned post-procedural care and ***inform policy discussions*** regarding reimbursement policies for stone disease. Finally, understanding the incidence, variation and financial impact of unplanned post-procedural care may help identify potential ***healthcare quality issues*** in the treatment of patients with stone disease.

Preliminary Studies

Our specific aims require substantial expertise in analysis of large datasets and understanding of epidemiology and patterns of care for urinary lithiasis. This section describes related research by the applicant.

Administrative claims data are designed for non-research purposes, and therefore unique challenges exist when using these data to address clinical and health services questions. Our investigative team has significant experience in linking and analyzing administrative claims and complex survey data. The applicant, **Scales**, has published several manuscripts using administrative claims and survey data, including analyses using National Ambulatory Medical Care Survey (NAMCS)[11], the Behavioral Risk Factor Surveillance System (BRFSS)[12], the Nationwide Inpatient Sample (NIS)[13], the National Health and Nutrition Examination Survey (NHANES)[2] and commercial and government administrative claims data.[14, 15] A summary of work relevant to the present proposal follows.

In a previous collaboration with the Urologic Diseases in America Project, **Scales**(2011) used administrative claims data to examine practice patterns and outcomes of surgical intervention for urinary lithiasis.[14] This investigation found that 38% of patients undergoing an initial shock wave lithotripsy (SWL) procedure subsequently underwent a second stone removal procedure within 120 days in a nationally representative sample of beneficiaries. On multivariable analysis, the odds of additional therapy following shock wave lithotripsy were 1.54 times that of initial ureteroscopic intervention. While the optimal rate of secondary treatment following SWL is unclear, given the higher expense associated with SWL versus ureteroscopy, these findings may have significant implications for cost management of urinary lithiasis.

In collaboration with the Urologic Diseases in America Project, **Scales** (2012) used data from NHANES to evaluate the current prevalence of kidney stones in the United States.[2] In addition, multivariable models were used to identify health characteristics such as obesity associated with a reported history of kidney stones. This investigation found that the prevalence of kidney stones in the United States has nearly doubled in the past 15 years, from approximately 1 in 20 persons in the mid-1990s to approximately 1 in 11 persons in 2010. In addition, the study noted strong associations between obesity, diabetes and a history of kidney stones, suggesting that the dramatic rise in the prevalence of obesity in the United States is contributing to the sharp increase in the prevalence of kidney stones.

Little is known regarding hospital readmissions and ED visits within 30 days of procedures to treat benign urologic conditions generally, and patients with stones in particular. One study using Medicare data compared 22 procedures performed either in a hospital setting, or in an office/ambulatory surgery center setting, and found that same day admission was higher in the office/ambulatory center setting.[10] However, this study did not include ureteroscopy or PNL procedures, nor did it examine patients aged less than 65 years. Another descriptive study using SEER-Medicare data examined 30 day readmissions following radical prostatectomy and radical cystectomy.[16] Neither of these studies characterized ED care following procedural intervention, which may be an important cost center for unplanned follow-up care. However, both studies suggest that it is feasible to investigate the topic of unplanned inpatient and ED care within 30 days of stone procedures.

Research Design and Methods

Data Source

We propose to conduct the analyses in the Marketscan dataset, which includes over 170 million lives covered by private insurers. This dataset contains information on medical claims, pharmacy claims, geographic location and benefit structure. Given the high prevalence of kidney stones in a working age, insured population, these data will be ideally suited to characterize the burden and impact of unplanned post-procedural care.

Study Cohort

The study cohort will consist of beneficiaries who undergo a procedure (shock wave lithotripsy, ureteroscopy or percutaneous nephrostolithotomy, see Table) for management of a kidney or ureteral stone between 1/1/2006 and 12/31/2010. The **primary outcome** will be an ED visit or hospital admission within 30 days of the procedure date (for ambulatory/outpatient procedures) or discharge date (for inpatient procedures).

Table. Administrative claims codes used to identify patients in the study cohort.

ICD9 Diagnostic Code	**Description**
270.0	Disturbance of amino acid transport
271.8	Hyperoxaluria
274.11	Uric acid nephrolithiasis
592.0	Calculus of Kidney
592.1	Calculus of Ureter
592.9	Urinary calculus, unspecified
ICD9 Procedure Codes	**Description**
55.04	Percutaneous nephrostomy with fragmentation
55.92	Repeat nephroscopic removal during current episode
56.0	Transurethral removal of obstruction from ureter and renal pelvis
59.95	Ultrasonic fragmentation of urinary stone
98.51	Extracorporeal shock wave lithotripsy (ESWL)
CPT-4 Procedure Codes	**Description**
50080	Percutaneous nephrostolithotomy, up to 2 cm
50081	Percutaneous nephrostolithotomy, over 2 cm
50590	Lithotripsy, extracorporeal shock wave
52352	Cystourethroscopy with ureteroscopy or pyeloscopy; with removal or manipulation of calculus (ureteral catheterization is included
52353	Cystourethroscopy with ureteroscopy or pyeloscopy; with lithotripsy (ureteral catheterization is included)

Covariates

A number of potential patient and provider characteristics may be associated with utilization or costs of unplanned post-procedural care. Patient characteristics will include age, sex, and co-morbid conditions (race is not available in Marketscan data). Socioeconomic indicators will include household income and education. Household income and education level may be estimated at the ZIP code level. Comorbid conditions will be identified using established claims-based algorithms and summarized as a Charlson score for analytic purposes, unless sample size permits specification of individual conditions.[17, 18] Providers in the top decile of unique patients treated will be designated *high volume providers*. These providers may possess special expertise in management of stone disease, and therefore outcomes of care (such as unplanned visits) may differ in important ways. Similarly, facilities in the top decile of unique patients treated will be designated *high volume facilities.* These facilities may deliver care differently than lower volume facilities, and therefore outcomes of care (i.e., unplanned post-procedure visits) may differ in important ways. Geographic region will also be included due to well-established variation in the epidemiology of stone disease as well as practice patterns. In addition, local healthcare resources (such as the number of urologists per capita) may influence the probability of unplanned post-procedural care. Specifically, patients living in areas with poor access to urologic care may be more likely to experience unplanned post-procedural visits (inpatient admissions or ED visits).

Analysis

Aim 1 – Incidence: The proportion of subjects who are admitted to inpatient care or visit an ED within 30 days from the date of the intervention will be calculated. In addition to calculating overall incidence, the proportion of subjects who require unplanned post-procedure inpatient care will be stratified by the initial procedure (i.e. shock wave lithotripsy, ureteroscopy, percutaneous nephrostolithotomy).

Aim 2 – Variation: We will construct multivariable logistic regression models to compare patient, provider and facility characteristics between those subjects who require unplanned post procedural inpatient/emergent care and those who do not. The **primary outcome** will be the occurrence of an ED visit or hospital admission within 30 days of the initial procedure (or within 30 days of discharge for inpatient procedures). If the findings under Aim 1 suggest important differences in the rate of unplanned post-procedural care related to the initial procedure, and sample size permits, then we will construct separate models for each of the three procedures. Models will use a random effects framework to account for clustering of outcomes at the facility and provider level.

Aim3 – Cost: We will compare total healthcare expenditures between those who require unplanned post-procedural care and those who do not. A multivariable regression model will be used to control for observed differences between the two groups. Covariates will include demographic variables (e.g. age, sex) and comorbid conditions as identified from medical claims. Comorbid conditions will be individually specified if sample size permits, otherwise a summary comorbidity score will be utilized. Benefits data, if available, will be used to control for the generosity of medical and pharmacy coverage. A multivariable model will be used to predict total cost of care for the episode, including the initial intervention as well as any care related to an unplanned visit within 30 days of the first intervention.

Limitations

A number of potential limitations must be considered for the proposed investigations. First, use of the Marketscan dataset, while optimal for examining a patient population with a high incidence of stone disease, lacks certain data regarding patient race, and provider/facility identifiers that could be linked to provider or facility characteristics. For example, a prior UDA analysis from the applicant demonstrated that more recently trained urologists were more likely to employ ureteroscopy than SWL. However, data from a private payer source will likely be more generalizable to the majority of patients with kidney stones. An alternate approach would be to perform a parallel analysis in Medicare data to address these questions.

Second, classification bias may exist; some hospital admissions within 30 days of a given procedure may be planned. For example, some urologists may performed staged or 'second look' PNL procedures. To address this problem, we will examine the frequency of admissions and ED visits by day over the 30 day window following the procedure, and potentially use sensitivity analyses excluding hospital admissions where a second stone removal procedure occurs.

Third, selection bias could potentially influence the probability of an unplanned post-procedural visit. For example, patients with higher surgical risks (and presumably higher readmission risk) could be selected for different procedures or care settings. We will attempt to minimize the influence of selection bias through the use of well-established statistical techniques, such as propensity score methods. Propensity score methods would rely on a multivariable model developed to identify observed patient characteristics associated with receipt of a specific procedure.

Finally, unmeasured confounding could influence observed associations between procedure, patient or other characteristics associated with unplanned post-procedural emergent or inpatient care. One way to address this issue is to use instrumental variable techniques. The success of this technique relies upon identification of an appropriate instrumental variable. Traditional instruments, such as distance between patient and provider, may not function well as an instrument in this analysis, since it is plausible that patients at greater distance from a provider may more likely to seek unplanned post-procedural care in an ED or local hospital, due to a lack of local urology care. Data elements contained within Marketscan data, as well as the Area Resource File, will be closely examined for variables that could serve as plausible instruments.

Draft Table Shells

Draft Table Shell 1. Baseline Characteristics of Study Population

Conceptual Variable	Data Source	Analytic Variable	No Unplanned Visit	Unplanned Visit	p value
N					
Age [Mean,SD]	Marketscan	AGE			
Gender, Male	Marketscan	SEX			
Initial Procedure	Marketscan	PROCn			
SWL	--	--			
URS	--	--			
PNL	--	--			
Income[1]	Area Resource File	Household income for ZIP			
Education[2]	Area Resource File	Average education for ZIP			
Comorbidity[3]	Marketscan	Charlson Score			
High Volume Provider	Marketscan	Procedure decile			
High Volume Facility	Marketscan	Procedure decile			
Region	Marketscan	REGION			
Northeast	--	--			
Midwest	--	--			
South	--	--			
West	--	--			

SD = Standard Deviation, SWL = shock wave lithotripsy, URS = ureteroscopy, PNL = percutaneous nephrostolithotomy

[1] County level average household income

[2] County level percent of population with at least high school graduate education

[3] Summary measure (i.e. Charlson score). If sample size permits, comorbid conditions will be listed individually.

Draft Table Shell 2. Characteristics associated with unplanned post-procedure visit (multivariable model).

Variable	Odds Ratio	95% CI
Age		
Gender, Male		
Initial Procedure		
SWL		
URS		
PNL		
Income[1]		
Education[2]		
Comorbidity[3]		
High Volume Provider		
High Volume Facility		
Region		
Northeast		
Midwest		
South		
West		

For data source of individual variables, please see draft table shell 1.

[1] County level average household income

[2] County level percent of population with at least high school graduate education

[3] Summary measure (i.e. Charlson score). If sample size permits, comorbid conditions will be listed individually

Draft Table Shell 3. Estimated total annual healthcare expenditures ($), per person per year, with and without unplanned post-procedure visit (multivariable model)

	No Unplanned Visit	**Unplanned Visit**
All		
Age		
18-44		
45-54		
55-64		
Gender		
Male		
Female		
Region		
Northeast		
Midwest		
South		
West		

References

1. Stamatelou KK, Francis ME, Jones CA, Nyberg LM, Curhan GC. Time trends in reported prevalence of kidney stones in the United States: 1976-1994. *Kidney Int.* May 2003;63(5):1817-1823.

2. Scales CD, Jr., Smith AC, Hanley JM, Saigal CS. Prevalence of Kidney Stones in the United States. *Eur Urol.* Mar 31 2012.

3. Ljunghall S. Incidence of upper urinary tract stones. *Miner Electrolyte Metab.* 1987;13(4):220-227.

4. Litwan MS, Saigal C. Urologic Diseases in America. In: Services UDoHaH, ed. Washington, DC: US Government Printing Office; 2012.

5. Litwin MS, Saigal CS. *Introduction*. Washington, DC: US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases.; 2007.

6. Litwin MS, Saigal C. Urologic Diseases in America. In: Services UDoHaH, ed. Washington, DC: US Government Printing Office; 2012.

7. Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. *N Engl J Med.* Apr 2 2009;360(14):1418-1428.

8. Epstein AM. Revisiting readmissions--changing the incentives for shared accountability. *N Engl J Med.* Apr 2 2009;360(14):1457-1459.

9. Joynt KE, Jha AK. Thirty-day readmissions--truth and consequences. *N Engl J Med.* Apr 12 2012;366(15):1366-1369.

10. Hollingsworth JM, Saigal CS, Lai JC, Dunn RL, Strope SA, Hollenbeck BK. Surgical quality among Medicare beneficiaries undergoing outpatient urological surgery. *J Urol.* Oct 2012;188(4):1274-1278.

11. Scales CD, Jr., Curtis LH, Norris RD, Schulman KA, Albala DM, Moul JW. Prostate specific antigen testing in men older than 75 years in the United States. *J Urol.* Aug 2006;176(2):511-514.

12. Scales CD, Jr., Curtis LH, Norris RD, Schulman KA, Dahm P, Moul JW. Relationship between body mass index and prostate cancer screening in the United States. *J Urol.* Feb 2007;177(2):493-498.

13. Scales CD, Jr., Curtis LH, Norris RD, et al. Changing Gender Prevalence of Stone Disease. *J Urol.* Mar 2007;177(3):979-982.

14. Scales CD, Jr., Krupski T, Curtis LH, et al. Practice Variation in the Surgical Management of Urinary Lithiasis. *Journal of Urology.* 2011;in press.

15. Scales CD, Jr., Calhoun EA, Assimos D, et al. Practice Patterns in Surgical Therapy for Urinary Lithiasis. Paper presented at: American Urological Association2008; Orlando, Florida.

16. Jacobs BL, Zhang Y, Tan HJ, Ye Z, Skolarus TA, Hollenbeck BK. Hospitalization Trends After Prostate and Bladder Surgery: Implications of Potential Payment Reforms. *J Urol.* Nov 16 2012.

17. Quan H, Sundararajan V, Halfon P, et al. Coding algorithms for defining comorbidities in ICD-9-CM and ICD-10 administrative data. *Med Care.* Nov 2005;43(11):1130-1139.

18. Birman-Deych E, Waterman AD, Yan Y, Nilasena DS, Radford MJ, Gage BF. Accuracy of ICD-9-CM codes for identifying cardiovascular and stroke risk factors. *Med Care.* May 2005;43(5):480-485.